

## **AR 70-25, Use of Volunteers as Subjects of Research, 25 Jan 90**

**Interim Management Control Evaluation.** *AR 70-25 is under revision. This evaluation should be used until publication of the revised AR 70-25 that will include an evaluation of key management controls.*

### **Appendix X**

#### **Management Control Evaluation**

X-1. Function. The function covered by this evaluation is research involving human subjects conducted or funded by the Army, not including research under the Clinical Investigation Program, which is regulated by AR 40-38. This evaluation should be used at the following levels: MACOM and INSTL.

X-2. Purpose. The purpose of this evaluation is to assist assessable unit managers and subject matter experts in evaluating the key management controls listed below. It is not intended to cover all controls.

X-3. Instructions. Answers must be based on the actual testing of key management controls (e.g., document analysis, direct observation, sampling, simulation, other). Answers which indicate deficiencies must be explained and corrective action indicated in supporting documentation. These management controls must be evaluated at least once every five years. Certification that this evaluation has been conducted must be accomplished on DA Form 11-2-R (Management Control Evaluation Certification Statement).

#### **X-4. Test Questions.**

- a. Are research activities involving human subjects identified within the Army organization conducting or funding research?
- b. Is non-exempt research reviewed by an Institutional Review Board (IRB)?
- c. Is the membership of the IRB(s) of record consistent with requirements of 32 CR 219?
- d. Is a procedure in place to ensure that IRB members are free of conflicts of interest?
- e. If informed consent cannot be waived under 32 CFR 219, is voluntary informed consent obtained from each subject or the subject's legal representative?
- f. Does the IRB of record determine the risk level of research protocols?
- g. Does the IRB review research to ensure that risks are minimized and are reasonable in relation to anticipated benefits?
- h. Are medical monitors appointed (or is such appointment expressly waived by the IRB) for greater-than-minimal-risk research?
- i. Is research approved at the appropriate Command level after IRB approval?
- j. Is research forwarded for second-level review, if appropriate?

k. Are decisions by the IRB(s) of record to suspend or terminate research honored by the organization conducting or funding the research?

l. Are investigators qualified to conduct research involving human subjects?

m. Does the IRB ensure that investigators are free from conflicts of interest?

n. Is a system in place to ensure appropriate storage and confidentiality of research records?

o. Does the IRB of record ensure that research is in compliance with 10 USC 980, FDA regulations, and 45 CFR 46, subparts B,C, and D, and DODD 3216.2?

p. Does the IRB of record conduct continuing review of research in accordance with 32 CFR 219?

X-5. Supersession. No prior version of this evaluation has been published.

X-6. Comments. Help make this a better tool for evaluating management controls.

Submit comments to: Department of the Army, Office of the Surgeon General (DASG-ZA), 5109 Leesburg Pike, Falls Church, VA 22041-3258